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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,753	12/19/2001	Jayarama K. Shetty	GC695	2084

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,753	Applicant(s) SHETTY ET AL.	
	Examiner Francisco C. Prats	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-18,21-34,37-51 and 53-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-18,21-34,37-51 and 53-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 5, 2006, has been entered.

Claims 1, 2, 6-18, 21-34, 37-51 and 53-61 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102/103

Claims 47-51 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Antrim et al (U.S. Pat. 5,322,778). The reference discloses a liquefied starch product which appears to be identical to the presently claimed product, based on the fact that the prior art product is a starch liquefact having a DE of 10.05, which is within the range recited in the claims, and a pH of 4.50, within the range recited in the claims, and being produced by an enzyme having essentially the same hydrolytic

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properties as the enzyme recited in the claims. See, e.g., Antrim at column 7, lines 1-42.

It is noted that claim 1 has been amended to recite that the enzyme treatment step must be conducted without the addition of bisulfite. Of the product-by-process claims presently recited, only claim 46 depends from claim 1, so this new limitation affects claim 46 only. However, claims 47-51 do not contain this new limitation. Thus claims 47-51 are still considered to be anticipated by Antrim.

It is further noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, the fact remains that the claims recite a product made by contacting the same starting material as the prior art, under the same conditions as in the prior art, with the same enzyme as the prior art. Consequently, even if the process results in the desired product more quickly, the claimed liquefied starch product still appears to be anticipated by the reference.

It is noted that the enzyme used to produce the claimed product is from a different species of microorganism than the prior art enzyme. However, even if this results in a nominal difference between the reference product and the claimed product such that there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product

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obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected nominal differences between starch liquefact products based on normal process variations between different hydrolysis batches and differences in enzyme batches. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding the propriety of this type of alternative rejection, note that MPEP 2113 states that:

. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP 2113 also clearly states that

The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. It is noted, as argued by applicant, that claim 1 now

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excludes the use of bisulfite in the enzymatic treatment step. However, only product-by-process claim 46 depends from claim 1. Thus, applicant's argument regarding the new limitation is irrelevant to claims 47-51, because those claims do not contain any limitation excluding the bisulfite used in Antrim. The rejection over Antrim is therefore still properly applied to claims 47-51.

Claims 46-51 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Liaw et al (U.S. Pat. 6,136,571).

The reference discloses a liquefied starch product which appears to be identical to the presently claimed product, based on the fact that the prior art product is a starch liquefact having a DE of 10-15 which is within the range recited in the claims, and a pH of below 4.50, encompassing the range recited in the claims, and being produced by an enzyme having essentially the same hydrolytic properties as the enzyme recited in the claims. See Liaw at column 1, line 61 to column 2, line 10, disclosing liquefaction to DE of 10-15, followed by adjusting the pH to below 4.5; see also column 15, lines 5-7, disclosing the use of a maltodextrin having a DE of 10 and a pH of 4.5 in the measurement of the half life of a glucoamylase.

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It is noted that claim 1 has been amended to recite that the enzyme treatment step must be conducted without the addition of bisulfite. Liaw does not disclose the presence of a bisulfite in the disclosed products. Thus claims 46-51 are considered to be anticipated by Liaw.

It is further noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, the fact remains that the claims recite a product made by contacting the same starting material as the prior art, under the same conditions as in the prior art, with the same enzyme as the prior art. Consequently, even if the process results in the desired product more quickly, the claimed liquefied starch product still appears to be anticipated by the reference.

It is noted that the enzyme used to produce the claimed product is from a different species of microorganism than the prior art enzyme. However, even if this results in a nominal difference between the reference product and the claimed product such that there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected nominal differences between starch liquefact products based on normal process variations.

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between different hydrolysis batches and differences in enzyme batches. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-18, 21-34, 37-51 and 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)) in view of JP 10-136979.

Shetty discloses a process of preparing glucose from starch, said process using the claimed process parameters. See, e.g. pages 6 and 14. Note in particular the disclosure on page 6 of the desirability of a liquefact having a DE of 10 to 12. Shetty differs from the claims in that Shetty uses a different α -amylase enzyme than that recited in the claims. However, Shetty discloses that α -amylases active at acidic pH are advantageous in processes of producing glucose from starch. Specifically, the liquefaction step is improved by decreasing chemical demand for pH adjustment, reducing color and by-product formation, and lowering refining requirements and costs (Shetty, page 7). Also, the lower pH afforded by the use of acidophilic

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α -amylase eliminates the undesirable formation of maltulose (Shetty, page 8). Shetty also discloses that enzymes which do not require calcium or stability are advantageous, as are relatively thermostable enzymes. Shetty, page 11, last sentence. ("It is evident from the above data that an improved thermostable alpha-amylase which can operate at a pH below 6.0 and at lower or no calcium will significantly reduce refining costs and improve the final glucose yield.")

As is evident from the English translation, JP '979 discloses an α -amylase which meets exactly the criteria disclosed by Shetty as being desirable and advantageous for use in the disclosed process of preparing glucose from starch. Specifically, the enzyme is thermostable, acid-stable, optimally active at a pH of about 4, and does not require calcium for activity (see Table 2). Thus, the artisan of ordinary skill practicing Shetty's process clearly would have recognized that the enzyme disclosed by JP '979 possesses all the properties required for use in Shetty's process. The artisan of ordinary skill would therefore clearly have been motivated to have used the enzyme of JP '979 in Shetty's process. A holding of obviousness is therefore required.

Because it is not clear that the enzyme units used in JP '979 correspond to the units used in applicant's claims, it is

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not clear that either reference discloses the use of the claimed amount of amylase. However, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that the rate of the liquefaction would have been readily optimized, depending on the amount of enzyme used. Thus, the claimed amounts of enzyme must be considered obvious in view of the fact that enzyme concentration was known to be a result-effective parameter, and therefore routinely optimized by artisan of ordinary at the time of applicant's invention.

Lastly, it is again noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, it is respectfully submitted that this limitation does not serve to distinguish the claims from the cited prior art. Specifically, it is noted that at 75 minutes the DE of the various liquefaction processes disclosed by Shetty is about 9, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12." See page 14 of Shetty, especially figs. 2 and 3. Moreover, the speed of an enzymatic reaction can be increased simply by increasing the ratio of enzyme to substrate, that is, by increasing the amount of enzyme or decreasing the amount of substrate. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill had a reasonable expectation that the

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claimed DE could be reached in the claimed amount of time by following the teachings of Shetty and JP '979. A holding of obviousness is therefore required.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant urges that Shetty fails to provide a reasonable expectation of success, at best providing making the claimed processes "obvious to try." However, Shetty discloses the desirability in starch liquefaction processes of using an enzyme having the exact properties of the enzyme described by JP '979. Contrary to applicant's argument, Shetty does in fact state how the process should be conducted by saying that an enzyme capable of liquefaction at acidic pH should employed in a liquefaction conducted at acidic pH. Respectfully, the clarity of Shetty's disclosure, combined with that of JP '979, goes well beyond "obvious to try."

Regarding Shetty's two-stage liquefaction being different than that claimed by applicant, note specifically that applicant's claims recite the process in "open" comprising language, which encompasses any additional steps, including those present in the Shetty process. Moreover, the liquefaction shown on page 5 is not the only liquefaction process disclosed by Shetty. The liquefaction processes graphically depicted on

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page 14 of Shetty all have a single addition of enzyme resulting in the claimed DE values, thus meeting this limitation in applicant's claims.

Moreover, applicant is in error by suggesting that all of the claims require a single addition of enzyme. In fact, only claims 1, 2, 6-16 recite a "single addition" of enzyme, and claims 33, 34 and 37-42 recite a "single liquefaction step process for starch." This leaves process claims 17, 18, 21-32, 43-45 and 53-61, which do not recite such a limitation, contrary to applicant's argument. Thus, applicant's argument regarding a single step process is irrelevant to process claims 17, 18, 21-32, 43-45 and 53-61, as well as being irrelevant to product-by-process claims 46-51. As to claims 1, 2, 6-16, 33, 34 and 37-42, it is again noted that those processes are recited in open "comprising" language, which does not exclude process steps not mentioned by the claims. If applicant considers the claims to recite a process "consisting" of a single addition of enzyme, then the claims should so state.

As to whether a DE of 10-12 can be reached at the claimed pH in the claimed amount of time, as applicant is surely aware, it is textbook knowledge that the speed of an enzyme reaction can be increased (up to V_{max}) by increasing the ratio of enzyme to substrate. Thus, the rejection of record being an

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obviousness rejection rather than an anticipation rejection, the artisan of ordinary skill, recognizing the fact that the rate of an enzyme reaction could be increased by increasing the ratio of enzyme to substrate, clearly would have been motivated to have used that technique to increase, or at least optimize, the rate of the reaction described by Shetty. At the very least, in view of the fact that the majority of the claims do not recite any limitation with respect to enzyme amount, applicant is incorrect in arguing that the claims recite any result unexpected from the cited prior art with respect to reaction rate. Moreover, with respect to those claims reciting enzyme amounts, a number of those claims (e.g. claim 9) recite only minimum amounts, therefore encompassing very large amounts of enzyme which would in fact be expected to generate fast enzyme reaction rates. Further still, with respect to those claims reciting maximum enzyme amounts (e.g. claim 13), there is nothing on the record indicating that the claimed enzyme behaves in any manner unexpected from the disclosures of the cited prior art.

With respect to the disclosure in JP '979 of adjusting the pH before adding enzyme, supposedly being different from the claims under examination, it is respectfully pointed out that only claims 54 and 56 specifically exclude pH adjustment **before** enzyme addition. The rest of the pending process claims only

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exclude pH adjustment during the contacting step. Thus, applicant's argument about this limitation is irrelevant to all but two pending claims. With respect to those claims, as has been pointed out previously, if one were to use the enzyme disclosed by JP '979 in Shetty's process, one would not have to adjust the pH to an acidic one, since the pH was already at that level. Specifically, Shetty clearly discloses that refined starch from the wet milling of grain enters the liquefaction process at pH 4.0 to 5.0. See Shetty at page 7. Shetty also discloses that liquefaction at that pH range would be advantageous because it would reduce the chemical demand for pH adjusting agents. See, *id.* Thus, by using the JP '979 enzyme in the liquefaction process of Shetty, one would not need to adjust the pH. Avoidance of the pH adjustment step is clearly described by Shetty as being advantageous. Moreover, the artisan of ordinary skill would have been motivated to have used the JP '979 enzyme in Shetty's pH 4.0 to 5.0 liquefaction process, since Shetty's preferred pH range is the exact pH optimum of the JP '979 enzyme. Moreover, as discussed above, the single enzyme addition is disclosed at least by Shetty. Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based

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on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

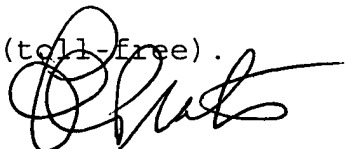
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP